# PEC UPDATE

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## ISSUE HIGHLIGHTS



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## Pharmacy Business Process Improvements Universal Pharmacy Patient Profile (UP$^3$)

In May 1993 a Tri-Service/Health Affairs Pharmacy Business Process Improvement (BPI) Analysis Project was completed. A work group of Air Force, Army, and Navy pharmacists involved in the project identified 32 business process improvements for the functional area of pharmacy within the DoD. BPI number 7 identified the need for a single, integrated, easily accessible pharmacy patient profile. The Pharmacy BPI Analysis Project indicated that a significant return on investment from a universal pharmacy patient profile (UP$^3$) was likely based on the contributions it would make towards supporting readiness, quality of health care delivery, reductions in costs of health care, and increases in patient and provider satisfaction.

The Pharmacoeconomic Center (PEC) was given the responsibility for further analysis of BPI number 7 in 1995. A multi-disciplinary team consisting of pharmacists from three services, an Air Force nurse, an Army physician, and a Navy comptroller was given the task of developing a Functional Economic Analysis (FEA) of UP$^3$. The work group analyzed the costs and benefits associated with UP$^3$, determined how UP$^3$ would interface with other systems (both current and future), established the information systems and data requirements necessary, and recommended options for implementation.

The objectives of the UP$^3$ are to consolidate current and historical patient information at the provider's fingertips to assist in clinical decision-making; to allow patients with active prescriptions to obtain refills at any Military Health Services System (MHSS) pharmacy regardless of where the original prescription was written; to support the readiness mission; to enhance patient and provider satisfaction; and to reduce overall MHSS drug-related costs.

The UP$^3$ initiative will provide an electronic pharmacy patient

profile in a central database that can be accessed on-line in real-time by all providers throughout the MHSS. Implementing UP$^3$ will generate significant qualitative and quantitative benefits in readiness, quality of patient care, cost reductions, and patient and provider satisfaction.

The UP$^3$ will improve readiness by:
- Identifying medication and immunization needs for personnel pre- and post-deployment
- Identifying medical deployability
- Projecting and identifying medication costs of deployment
- Contributing to continuity of care as patients move through theaters of operation.

The UP$^3$ will improve quality of patient care by:
- Improving the quality of the patient-provider encounter
- Supporting a uniform, consistent pharmacy benefit
- Providing real-time clinical information through open architecture
- Monitoring prescribing trends and outcomes
- Allowing for data comparison across the MHSS
- Targeting education and training opportunities.

The UP$^3$ will reduce cost by:
- Decreasing waste, duplication, and abuse
- Maximizing economies of scale through capture of MHSS prescription cost data
- Promoting cost-effective prescribing
- Reducing medical litigation.

The UP$^3$ will increase satisfaction by:
- Allowing patients to obtain prescription services at any MHSS pharmacy
- Supporting uniform, consistent drug availability throughout the MHSS
- Integrating patient and medication information from worldwide pharmacy and other clinical databases
- Reducing administrative tasks
- Reducing unnecessary patient visits
- Streamlining patient visits.

The FEA, completed in November 1995, demonstrated a 5:1 return on investment. The contribution of the FEA was deemed significant by the Defense Medical Information Management (DMIM) office at Health Affairs resulting in additional funding to continue the development of functional and technical requirements for the pharmacy system of the future.

The UP$^3$ work group reconvened in FY 96 to establish functional and technical requirements for a new pharmacy system that is compliant with the DoD Automated Information Systems (AIS) architecture. The baseline for establishing the functional and technical requirements is the current CHCS pharmacy system, which was then expanded to incorporate additional features. The system required to meet the objectives described in the FEA must, by definition, be very robust, flexible, and easy-to-use. It must be accessible through integration with current MHSS systems, yet capable of operating in the latest evolving technology environments. Health Affairs requires a system that meets its functional and technical goals, policies, and standards.

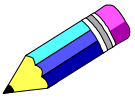
Additionally, the UP$^3$ work group completed a market analysis of commercial off-the-shelf (COTS) pharmacy systems to determine whether any system was capable of performing in the robust, flexible environment that is defined in the requirements. The group discovered over 60 vendors that provide pharmacy-type software packages. Through a continued process of evaluation, the work group concluded that nine vendors maintained technology sufficient to meet minimum requirements.

The UP$^3$ work group is finalizing the functional and technical requirements, and testing and acquisition plans. When completed, the requirements, and testing and acquisition plans will be used for official Request for Information (RFI) or Request for Proposal (RFP). As with most projects in today's fiscal environment, funding is the limiting factor.

One idea is crystal clear and central to all AIS initiatives: the DoD will have an open architecture automated system that is capable of upgrading without the need for total replacement in the future.

At some point in time, we will have a new pharmacy system replacing CHCS. The work that is being achieved by the current work group will ensure the replacement of the current pharmacy system with a major improvement in functionality when funding is available.

**Correction:**
**PEC Update 97-04**



The last page of PEC Update 97-04 (13 January 1997) describing the American College of Cardiology/American Heart Association acute myocardial infarction guidelines contained an error.

The second paragraph in the left column on page 4 should have read "Single reprints of the complete guidelines (reprint No. 71-0094) and executive summary (reprint No. 71-0092) are available by calling *1-800-253-4636* or 1-800-242-8721."

## In the Literature..... Treatment Guidelines and Consensus Statements

The following treatment guideline and consensus statement literature citations are provided for information purposes only.

American Society of Hematology
George JN, Woolf SH, Raskob GE, Wasser JS, Aledort LM, Ballem PJ, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. *Blood* 1996;88:3-40.

National Depressive and Manic-Depressive Association
Hirschfeld RMA, Keller MB, Panico S, Arons BS, Barlow D, Davidoff F, et al. The National Depressive and Manic-Depressive Association Consensus Statement on the undertreatment of depression. *JAMA* 1997;277:333-40.

The Expert Consensus Guideline Series, The Journal of Clinical Psychiatry
Frances A, Docherty JP, Kahn DA. Treatment of bipolar disorder. *J Clin Psychiatry* 1996;57(Suppl 12A): 1-89.

Frances A, Docherty JP, Kahn DA. Treatment of schizophrenia. *J Clin Psychiatry* 1996;57(Suppl 12B): 1-59.

## 1997 Ambulatory Care Pharmacist Conference

The 1997 Ambulatory Care Pharmacist Conference sponsored by the Pharmacoeconomic Center was held January 26-29, 1997. Participants found the program to be educational and informational. The program was accredited for pharmacists and physicians, providing up to 13 hours of ACPE continuing pharmaceutical education credit and 12.5 hours of Category 1 Continuing Medical Education (CME) credit. Attendees included 53 pharmacists, 4 physicians, 2 other health care providers, and 15 sponsor representatives. The breakdown by federal sector included 24 Army personnel, 11 Air Force personnel, 3 Navy personnel, 6 Public and Indian Health Service personnel, and 11 PEC staff members.

## Recommended Childhood Immunization Schedule—1997

The following childhood immunization schedule (see page 4) has been approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). It indicates the recommended age for routine administration of currently licensed childhood vaccines. Some combination vaccines are available and may be used whenever administration of all components of the vaccine is indicated. This schedule does not necessarily represent DOD immunization policy. Please contact your local immunization clinic for the current DOD policy information.

## Recommended Childhood Immunization Schedule—January to December 1997

| Age⇒ / Vaccine⇓ | Birth | 1 month | 2 months | 4 months | 6 months | 12 months | 15 months | 18 months | 4-6 years | 11-12 years | 14-16 years |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Hepatitis B[1,2] | Hep B-1 | | | | | | | | | | |
| | | Hep B-2 | | | Hep B-3 | | | | | Hep B[2] | |
| Diphtheria, Tetanus, Pertussis[3] | | | DTaP or DTP | DTaP or DTP | DTaP or DTP | | DTaP or DTP[3] | | DTaP or DTP | Td | |
| *Haemophilus influenzae* type b[4] | | | Hib | Hib | Hib[4] | Hib[4] | | | | | |
| Polio[5] | | | Polio[5] | Polio | | Polio[5] | | | Polio | | |
| Measles, Mumps, Rubella[6] | | | | | | MMR | | | MMR[6] | MMR[6] | |
| Varicella-zoster virus[7] | | | | | | Var[7] | | | | Var[7] | |

Recommended vaccines are listed under the routinely recommended ages. Shaded bars indicate range of acceptable ages for vaccination. Heavy outlined bars indicate catch-up vaccination: at 11-12 years of age, hepatitis B vaccine should be administered to children not previously vaccinated, and varicella-zoster virus vaccine should be administered to unvaccinated children who lack a reliable history of chickenpox.

1 ***Infants born to hepatitis B surface antigen (HBsAg)-negative mothers*** should receive 2.5μg of Recombivax HB® (Merck) or 10 μg of Engerix-B® (SmithKline Beecham). The 2nd dose should be administered at least 1 month after the 1st dose. ***Infants born to HBsAg-positive mothers*** should receive 0.5 mL Hepatitis B Immune Globulin (HBIG) within 12 hours of birth, and either 5μg of Recombivax HB® or 10μg of Engerix-B® at a separate site. The 2nd dose of vaccine is recommended at 1 to 2 months of age and the 3rd dose at 6 months of age.
***Infants born to mothers whose HBsAg status is unknown*** should receive either 5 μg of Recombivax HB or 10 μg of Engerix-B within 12 hours of birth. The 2nd dose of vaccine is recommended at 1 month of age and the 3rd dose at 6 months of age. Blood should be drawn at the time of delivery to determine the mother's HBsAg status; if it is positive, the infant should receive HBIG as soon as possible (no later than 1 wk of age). The dosing and timing of subsequent vaccine doses should be based on the mother's HBsAg status.

2 Children and adolescents who have not been vaccinated against hepatitis B in infancy may begin the series during any childhood visit. Those who have not previously received three doses of hepatitis B vaccine should initiate or complete the series at the 11-12 year old visit. The 2nd dose should be administered at least 1 month after the 1st dose, and the 3rd dose should be administered at least 4 months after the 1st dose and at least 2 months after the 2nd dose.

3 DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is the preferred vaccine for all doses in the vaccination series, including completion of the series in children who have received at least one dose of whole-cell DTP vaccine. Whole-cell DTP is an acceptable alternative to DTaP. The 4th dose of DTaP may be administered as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose, and if the child is considered unlikely to return at 15 to 18 months of age. Td (tetanus and diphtheria toxoids, adsorbed, for adult use) is recommended at 11 to 12 years of age if at least 5 years have elapsed since the last dose of DTP, DTaP, or DT. Subsequent routine Td boosters are recommended every 10 years.

4 Three *H. influenzae* type b (Hib) conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB® - Merck) is administered at 2 and 4 months of age, a dose at 6 months is not required. After completing the primary series, any Hib conjugate vaccine may be used as a booster.

5 Two polio virus vaccines are currently licensed in the US: inactivated polio virus vaccine (IPV) and oral polio virus vaccine (OPV). The following schedules are all acceptable by the ACIP, the AAP, and the AAFP, and parent and providers may choose among them:

1. IPV at 2 and 4 months; OPV at 12-18 months and 4-6 years
2. IPV at 2, 4, 12-18 months, and 4-6 years
3. OPV at 2, 4, 6-18 months, and 4-6 years

The ACIP routinely recommends schedule 1. IPV is the only polio virus vaccine recommended for immunocompromised persons and their household contacts.

6 The 2nd dose of MMR is routinely recommended at 4-6 years of age or at 11-12 years of age, but may be administered during any visit, provided at least 1 month has elapsed since receipt of the 1st dose, and that both doses are administered at or after 12 months of age.

7 Susceptible children may receive varicella vaccine (Var) during any visit after 12 months of age. Unvaccinated persons who lack a reliable history of chickenpox should be vaccinated at the 11-12 years old visit. Susceptible persons 13 years of age and over should receive 2 doses at least 1 month apart.

*Adapted from:* Am Fam Physician 1997;55:342-6 and JAMA 1997;277:202-7.

# New Drug Approvals for 1996

The Food and Drug Administration (FDA) approved 53 new molecular entities during 1996. Of these approvals, 19 drugs were designated 1P drugs or new molecular entities that represent an advance over available therapy. These agents received a priority review. Of special note, one over-the-counter (OTC) product received a priority review (Bentoquatam, Ivy Block by EnviroDerm). The remaining 34 medications were classified as 1S drugs and received a standard review. The following table outlines the new molecular entity drug approvals for 1996. For information regarding new derivatives, formulations, or combinations of currently marketed products, or new indications for currently marketed products, see the FDA's Web site at: < http://www.fda.gov/cder/da/da.htm >.

| Generic Name (Brand Name - Sponsor) | Indication/Use | Approval Date |
|---|---|---|
| **1P Drugs (Priority Review)** | | |
| Albendazole (Albenza - SmithKline Beecham)† | Treatment of neurocysticerosis and hydatid disease | 6/11/96 |
| Amlexanox (Aphthasol - Block Drug Co.) | Treatment of signs and symptoms or aphthous ulcers | 12/17/96 |
| Atorvastatin calcium (Lipitor - Warner-Lambert) | Adjunct to diet to reduce elevated cholesterol and triglycerides in patients with primary hypercholesterolemia and mixed dyslipidemia, and to reduce cholesterol in patients with homozygous familial hypercholesterolemia | 12/17/96 |
| Bentoquatam (Ivy Block - EnviroDerm Pharmaceuticals) | Protects against poison ivy, poison oak, and poison sumac when applied before contact (OTC product) | 8/26/96 |
| Betaine (Cystadane - Orphan Medical)† | Treatment of homocystinuria to decrease elevated homocystine blood levels | 10/20/96 |
| Corticorelin ovine triflutate (Acthrel - Ferring Labs)† | Use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushing's syndrome | 5/23/96 |
| Docetaxel (Taxotere - Rhone-Poulenc Rorer)* | Treatment of patients with locally advanced metastatic breast cancer who have progressed or relapsed during anthracycline-based therapy | 5/14/96 |
| Donepezil (Aricept - Pfizer/Eisai) | Treatment of mild to moderate dementia of the Alzheimer's Type | 11/25/96 |
| Gemcitabine HCl (Gemzar - Lilly) | First-line treatment for patients with locally advanced or metastatic adenocarcinoma of the pancreas | 5/15/96 |
| Indinavir sulfate (Crixivan - Merck)* | Treatment of HIV infection in adults when antiretroviral therapy is warranted | 3/13/96 |
| Insulin lispro (Humalog - Lilly) | Treatment of patients with type I and II diabetes mellitus | 6/14/96 |
| Irinotecan HCl (Camptosar - Pharmacia & Upjohn) | Treatment of patients with metastatic carcinoma of the colon or rectum whose disease has progressed or recurred following 5-FU-based therapy | 6/14/96 |
| Ivermectin (Stromectol - Merck) | Treatment of strongyloidiasis and onchocerciasis | 11/22/96 |
| Latanoprost (Xalatan - Pharmacia & Upjohn) | For lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension intolerant to or unresponsive to other medications | 6/5/96 |
| Midodrine (ProAmatine - Roberts Pharmaceuticals)*† | Treatment of symptomatic orthostatic hypotension. | 9/6/96 |
| Nevirapine (Viramune - Boehringer Ingelheim) | Use in combination with nucleoside analogs for the treatment of HIV infected adults with clinical or immunological deterioration | 6/21/96 |
| Ritonavir (Norvir - Abbott)* | Treatment of patients with HIV infection in combination with nucleoside analogs or as monotherapy | 3/1/96 |
| Sodium phenylbutyrate (Buphenyl - Ucyclyd)† | Management of chronic urea cycle disorders | 4/30/96 |
| Topotecan HCl (Hycamtin - SmithKline Beecham) | Treatment of patients with metastatic ovarian cancer after failure of initial or subsequent chemotherapy | 5/28/96 |
| **1S Drugs (Standard Review)** | | |
| $^{13}C$ urea (UBT breath test - Meretek Diagnostics) | For detection of *Helicobacter pylori*-associated urease | 9/17/96 |
| Adapalene (Differin - Galderma Laboratories) | Topical treatment of acne vulgaris | 5/31/96 |
| Azelastine (Astelin - Carter-Wallace) | Treatment of symptoms of seasonal allergic rhinitis in adults and children $\geq$ 12 years of age | 11/1/96 |
| Brimonidine (Alphagan - Allergan) | For lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension | 9/5/96 |

| Generic Name (Brand Name - Sponsor) | Indication/Use | Approval Date |
|---|---|---|
| Butenafine HCl (Mentax - Penederm) | Topical treatment of interdigital tinea pedis | 10/18/96 |
| Cabergoline (Dostinex - Pharmacia & Upjohn) | Treatment of hyperprolactinemic disorders, either idiopathic or due to pituitary adenoma | 12/23/96 |
| Cefepime HCl (Maxipime - Bristol-Myers Squibb) | Treatment of urinary tract, skin and skin structure infections and moderate-to-severe pneumonia | 1/18/96 |
| Cidofovir (Vistide - Gilead Sciences) | Treatment of relapsing cytomegalovirus retinitis in patients with AIDS who have relapsed on, or cannot tolerate, existing therapies | 6/26/96 |
| Danaparoid sodium (Orgaran - Organon) | Prophylaxis of post-operative deep vein thrombosis elective hip surgery | 12/24/96 |
| Ferumoxides (Feridex - Advanced Magnetics) | Adjunct to MRI to enhance detection and evaluation of liver lesions associated with alterations of the reticuloendothelial system | 8/30/96 |
| Ferumoxsil (GastroMark - Advanced Magnetics) | For oral use with MRI to enhance the delineation of the bowel | 12/6/96 |
| Fexofenadine HCl (Allegra - Hoechst Marion Roussel) | Relief of symptoms associated with seasonal allergic rhinitis in adults | 7/25/96 |
| Fosfomycin tromethamine (Monurol - Forest/Zambon) | Single-dose therapy for treatment of uncomplicated urinary tract infection | 12/19/96 |
| Fosphenytoin (Cerebyx - Warner-Lambert) | Control of generalized convulsive status epilepticus, prevention and treatment of seizures during neurosurgery, and short-term substitute for oral phenytoin | 8/5/96 |
| Glatiramer acetate (Copaxone - Teva Pharmaceuticals) | Reduction of relapses in patients with relapsing-remitting multiple sclerosis | 12/20/96 |
| Iodixanol (Visipaque - Nycomed) | Contrast media | 3/22/96 |
| Meropenem (Merrem - Zeneca) | Treatment of complicated intra-abdominal infections, and bacterial meningitis in pediatric patients 3 months of age or older | 6/21/96 |
| Miglitol (Glyset - Bayer) | Adjunct to diet or diet plus sulfonylurea therapy to improve glycemic control in patients with Type II diabetes | 12/18/96 |
| Mirtazapine (Remeron - Organon) | Treatment of depression | 6/14/96 |
| Nilutamide (Nilandron - Hoechst Marion Roussel) | Use in combination with surgical castration for treatment of metastatic prostate cancer | 9/19/96 |
| Olanzapine (Zyprexa - Lilly) | Management of manifestations of psychotic disorders | 9/30/96 |
| Olopatadine (Patanol - Alcon) | For temporary prevention of itching of the eye due to allergic conjunctivitis | 12/18/96 |
| Penciclovir (Denavir - SmithKline Beecham) | Treatment of recurrent herpes labialis in adults | 9/24/96 |
| Pentosan polysulfate sodium (Elmiron - Ivax) | Relief of bladder pain or discomfort associated with interstitial cystitis | 9/26/96 |
| Remifentanil (Ultiva - Glaxo Wellcome) | Use as an analgesic during induction and maintenance of general anesthesia, for continuation into immediate post-operative period, or as a component of monitored anesthesia | 7/12/96 |
| Ropivacaine (Naropin - Astra) | Production of local and regional anesthesia for surgery, postoperative pain management, and obstetrical procedures | 9/24/96 |
| Sparfloxacin (Zagam - Rhone-Poulenc Rorer) | Treatment of community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis | 12/19/96 |
| Technetium Tc-99m tetrofosmin (Myoview - Medi-Physics) | Scintigraphic imaging of myocardium following administration under exercise and resting conditions | 2/9/96 |
| Tizanidine (Zanaflex - Athena Neurosciences) | For acute and intermittent management of increased muscle tone associated with spasticity | 11/27/96 |
| Topiramate (Topamax - Johnson & Johnson) | Adjunctive therapy for partial onset seizures in adults | 12/24/96 |
| Trandolapril (Mavik - Knoll) | Treatment of hypertension alone or in combination | 4/26/96 |
| Valsartan (Diovan - Novartis) | Treatment of hypertension | 12/23/96 |
| Zafirlukast (Accolate - Zeneca) | Prophylaxis and chronic treatment of asthma in adults and children $\geq$12 years of age | 9/26/96 |
| Zileuton (Zyflo - Abbott) | Prophylaxis and chronic treatment of asthma in adults and children $\geq$ 12 years of age | 12/9/96 |

* accelerated approval; † designated orphan drug

Adapted from: *F-D-C Reports* 1997;59(1):19-24 and the FDA Drug Approvals List on the Internet at: http://www.fda.gov/cder/da